

K121818
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5 - 510(k) Summary Statement as Required by Title 21CFR 807.92

FEB 7 2013

510(k) Submitter: Oxford Performance Materials, LLC
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South Windsor, CT 06074 USA
1-860-698-9300

Contact Person: Leigh Ayres, Director of Scientific & Regulatory Affairs
Date of 510(k) summary preparation: December 18, 2012
Proprietary Name: OsteoFab™ Patient Specific Cranial Device
Common or Usual Name: Patient Specific Cranial Implant
Classification: Title 21 CFR 882.5330; Preformed Non-Alterable Cranioplasty Plate; Class II
Panel: Neurology
Product Code: GXN
Predicate Devices: Kelynam Custom Skull Implant (K103582), Synthes Patient Specific Cranial Implant (K053199), Osteo-Symbionics Patient Specific Cranial Implant (K072601), MedCAD AccuShape PEEK Patient Specific Implant (K110684), and Osteo-Symbionics Patient Specific Cranial Implant (K121102)

Description of the Device

An OsteoFab™ Patient Specific Cranial Device (OPSCD) is built individually for each patient to correct defects in cranial bone. The OPSCD is constructed with the use of the patient's CT imaging data and computer aided design to determine the dimensions of each implant. The OPSCD is built by a LASER sintering machine. The OPSCD is attached to native bone with commercially available cranioplasty fixation systems. The OPSCD is a non-load bearing single use device and it is non-sterile. The sterilization instructions documented in the package insert have been validated.

Intended Use Statement

The OsteoFab™ Patient Specific Cranial Device (OPSCD) intended for the replacement of bony voids in the cranial skeleton.

Endotoxicity

Non-sterilized OsteoFab™ Patient Specific Cranial Device (OPSCD) test specimens were subjected to a Limulus Amebocyte Lysate (LAL) assay according to USP 85 and the results of the testing showed that bacterial endotoxin levels were lower than the detection limit of 2.15 EU/device.

Biocompatibility

Biocompatibility tests were selected according to the FDA guidance document: "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" (1995) and the test results obtained from test specimens were found to be within acceptance criteria described in the standards.

Performance Testing – Bench Testing

The test suite for the final quality control (QC) testing of the OsteoFab™ Patient Specific Cranial Device (OPSCD) includes glass transition temperature (Tg), Fourier transform infrared spectroscopy (FTIR), specific gravity, and tensile strength.

The final QC specifications for those tests were determined from 23 builds. TABLE 1 shows the mean, standard deviation, the standard deviation multiplied by three, the acceptance criteria, and the formula for the acceptance criteria.

TABLE 1: Summary Statistics of 23 Builds

| | Tg (20°C/min) | FTIR | Average Specific Gravity | Average Tensile Stress at Break (X- orientation) (KPSI) | Average Tensile Elongation @ Break (%) | Average Young's Modulus of Elasticity (KPSI) |
|--|------------------|--|--------------------------------|--|--|--|
| mean | 160.70 | 96.68 | 1.28 | 12.04 | 2.52 | 541.61 |
| SDEV | 2.10 | 0.73 | 0.01 | 1.10 | 0.35 | 93.89 |
| 3SD | 6.30 | 2.19 | 0.03 | 3.27 | 1.05 | 279 |
| Acceptance Criteria | 154-167 | ≥95% Match | 1.25-1.31 | ≥8.77 | ≤3.6% | ≥262 |
| Formula for the Acceptance Criteria | Mean +/- 3SD | ≥95% Match to a Designated PEKK Standard | Mean +/- 3SD | Mean - 3SD | Mean + 3SD | Mean - 3SD |

The OPSCD test specimens from the 23 builds which were subjected to tensile strength testing were 3.2 mm thick. In order to determine the minimum thickness for an OPSCD, three sets (5 specimens each) of tensile bars that were 1, 2, and 4 mm thick were built. The average tensile strength data for each size is compared to the final QC release acceptance criteria (see TABLE 2).

All three sizes (1, 2, and 4 mm) of test specimens are substantially equivalent to the 3.2 mm final QC test specimen because the data obtained was within the final QC acceptance criteria. Based on the measurements obtained, the minimum thickness of an OPSCD is 1 mm.

TABLE 2: Summary Statistics of the 1, 2, and 4 mm Thick Test Specimens

| Sample Description | Average Tensile Stress at Break (X-orientation) (KPSI) | Average Tensile Elongation @ Break (%) | Average Young's Modulus of Elasticity (KPSI) |
|---------------------------------------|--|--|--|
| 1 mm thickness (average) | 10.5 | 2.4 | 329 |
| 2 mm thickness (average) | 10.8 | 2.4 | 409 |
| 4 mm thickness (average) | 11.6 | 2.4 | 490 |
| Release Criteria for 3.2 mm thickness | ≥ 8.77 | ≤ 3.6 | ≥ 262 |

Test specimens were also built to determine the range of pore (through hole) sizes and the minimum spacing of through holes. These test specimens were 4 mm thick and each had more than 10 through holes. Based on the measurements obtained, the range of through holes that can be built is 2 mm to 5 mm and the minimum spacing of through holes is 2 mm. TABLE 3 and TABLE 4 show the average of the through hole size measurements and the average of the spacing between through hole measurements, respectively.

TABLE 3: Vernier Caliper Measurements of the Diameter of Through Holes

| | 5 mm Through Hole Test Specimen with 5 mm Spacing (Diameter in mm) | 2 mm Through Hole Test Specimen with 2 mm Spacing (Diameter in mm) |
|------------------------------|--|--|
| Average (n=10) | 4.74 | 1.92 |
| Standard Deviation | 0.03 | 0.05 |
| Nominal Value with Tolerance | 5.00 (4.50 – 5.50) | 2.00 (1.50 – 2.50) |

TABLE 4: Vernier Caliper Measurements of the Spacing between Through Holes

| | 5 mm Through Hole Test Specimen with 5 mm Spacing (Spacing in mm) | 2 mm Through Hole Test Specimen with 2 mm Spacing (Spacing in mm) |
|------------------------------|---|---|
| Average (n=10) | 4.81 | 1.79 |
| Standard Deviation | 0.02 | 0.03 |
| Nominal Value with Tolerance | 5.00 (4.50 – 5.50) | 2.00 (1.50 – 2.50) |

Substantial Equivalence Discussion

The OsteoFab™ Patient Specific Cranial Device (OPSCD) is substantially equivalent to five other preformed nonalterable cranioplasty plates: the Kelynam custom Skull Implant, the Synthes Patient Specific Cranial Implant, the Osteo-Symbionics Patient Specific Cranial Implant, the MedCAD AccuShape PEEK Patient Specific Implant, and the Osteo-Symbionics Patient Specific Cranial Implant.

The intended use statement for the OPSCD is within the scope of application for the five predicate devices. The intended use statements of the Synthes and Osteo-Symbionics devices apply to cranial and craniofacial bone. The intended use statement of the OPSCD is limited to cranial skeleton.

All five predicate devices are fabricated from polymers, each is custom sized to the patient, and they are sold non-sterile. The substantial equivalence information on the subject and predicate devices is summarized on the substantial equivalence matrix (TABLE 5). The substantial equivalence matrix shows that the characteristics listed for the subject (OPSCD) and the five predicate devices are substantially equivalent.

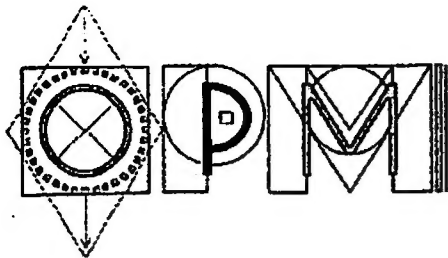


TABLE 5: Substantial Equivalence Matrix

| Characteristic | OsteoFab™ Patient Specific Cranial Device (Subject Device) | Kelyniam Custom Skull Implant (K103582) | Synthes Patient Specific Cranial Implant (K053199) | Osteo- Symbionics Patient Specific Cranial Implant (K072601) | MedCAD AccuShape PEEK Patient Specific Implant (K110684) | Osteo- Symbionics Patient Specific Cranial Implant (K121102) |
|-----------------------------|---|---|---|--|--|---|
| Intended Use | Replace bony voids in the cranial skeleton | Replace bony voids in the cranial skeleton | Replace bony voids in the cranial craniofacial skeleton | Corrects defects in craniofacial bone | Correct defects/replace bony voids in the cranial skeleton | Designed individually for each patient to correct defects in cranial bone |
| Materials | OXPEKK | PEEK-OPTIMA LT1 | PEEK Optima- LT1 | Polymethyl Methacrylate (PMMA) | PEEK | PEEK |
| Technical Specifications | Custom sized to each patient utilizing CT data | Custom sized to each patient utilizing CT data | Custom sized to each patient | Plate – custom sized to each patient | Custom sized to each patient utilizing CT data | Manufactured one at a time to custom-order based upon the patient's CT scan |
| Sterilization | Non-sterile | Non-sterile | Non-sterile | Non-sterile | Non-sterile | Non-sterile |

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Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

FEB 26 2013

Oxford Performance Materials
% Ms. Leigh Ayres
Director of Scientific and Regulatory Affairs
30 South Satellite Road
South Windsor, CT 06074

Re: K121818

Trade/Device Name: OsteoFab™ Patient Specific Cranial Device
Regulation Number: 21 CFR 886.5330
Regulation Name: Preformed nonalterable cranioplasty plate
Regulatory Class: Class II
Product Code: GXN
Dated: December 18, 2012
Received: December 28, 2012

Dear Ms. Ayres:

This letter corrects our substantially equivalent letter of February 7, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

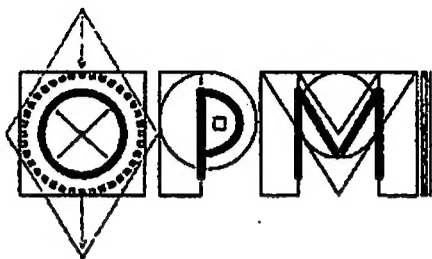
Sincerely yours,

Kesia Y. Alexander -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K121818



4 - Indications for Use Statement

510(k) Number (if known):

Device Name: OsteoFab™ Patient Specific Cranial Device

Indication for Use:

The OsteoFab™ Patient Specific Cranial Device (OPSCD) is intended for the replacement of bony voids in the cranial skeleton.

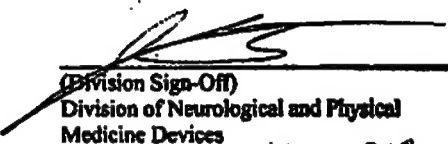
Prescription Use v
(Part 29 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(29 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Neurological and Physical
Medicine Devices
510(k) Number K121818

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